Exhibit 10

MEMORANDUM

TO: Distribution
FROM: R. Dennis Houlsby
DATE: 3-4-96
SUBJECT: Biocompatibility Test Results

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Biotesting has been completed on Polyaryletherketone (PEEK) 381 G from Acutech Plastics (Reading, PA) in the form of raw material/component/finished device for the following application(s): —

ACS Part # — Vendor Part # —
ACS Lot # — Vendor Lot # AP #03-522

	TEST	STERILE	RESULTS
☒	Cytotoxicity (MEM/Agar)	Yes (No)	(Pass)/Fail
☒	Hemolysis	Yes (No)	(Pass)/Fail
☐	USP Class IV	Yes/No	Pass/Fail
☐	AMES	Yes/No	Pass/Fail
☐	Other 1.	Yes/No	Pass/Fail
	2.	Yes/No	Pass/Fail
	3.	Yes/No	Pass/Fail

Based on the above results, the recommendations are as follows:

(A.) X The material may be used for further product development.
__ The finished device is judged biocompatible for short term exposure in the body and further testing is not required.

B.__ The device may be used for further product development or evaluation, although further tests are required, as outlined in the Comments Section below.

C.__ Further testing is required before the material may be considered biocompatible for use in the body:
1.
2.
3.

Additional Comments:
381G refers to the grade of the material.

R.D. Houlsby 3-4-96
Reviewer Date

Distribution: M. Flanagan, B. Rinaldi
K. Cherry

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LAB NO. 94C 04082 00
P.O. NO. AS413

ADVANCED CARDIOVASCULAR SYSTEM
P.O. BOX 58167
3200 LAKESIDE DRIVE
SANTA CLARA, CA 95052 8167
ATTN: R. DENNIS HOULSBY

ID NO. AP #03-522

CYTOTOXICITY - MEM ELUTION - MG023

Test Article: Peek 381 G

Test Article Size Used: 35.2 cm^2

Procedure: A monolayer of L-929 cells was grown to confluency and exposed to an extract of the test article prepared by placing the test article in 6 ml of 5% Minimum Essential Medium and extracting at 37°C for 24 hours. Duplicate MEM aliquots were used as negative controls. The positive control was extracted at 37°C for 24 hours and tested using an end-point titration procedure. After exposure to the extracts, the cells were examined microscopically for cytotoxic effect (CTE). Presence (+) or absence (-) of a confluent monolayer, vacuolization, cellular swelling and crenation and the percentage of cellular lysis were recorded.

CTE Score	Microscopic Appearance of Cells
Nontoxic (N)	A uniform, confluent monolayer, with primarily elongated cells, and discrete intracytoplasmic granules present at the 24 hour observation. At the 48 and 72 hour observation periods, there should be an increasing number of rounded cells as cell population increases and crowding begins. Slight or no vacuolization, crenation or swelling should be present.
Intermediate (I)	Cells may show marked vacuolization, crenation or swelling. Cytolysis (0-50%) of cells that results in floating cells and debris in the medium may be present. The remaining cells are still attached to the flask surface.
Toxic (T)	Greater than 50% of all cells have been lysed. Extensive vacuolization, swelling, or crenation are usually present in the cells remaining on the flask surface.

Results:

	Confluent Monolayer	Vacuolization	Swelling	Crenation	% Lysis	CTE Score
24 HOURS						
Test Medium	(+)	(-)	(-)	(-)	0	N
Neg. Controls	(+)	(-)	(-)	(-)	0	N
48 HOURS						
Test Medium	(+)	(-)	(-)	(-)	0	N
Neg. Controls	(+)	(-)	(-)	(-)	0	N
72 HOURS						
Test Medium	(+)	(-)	(-)	(-)	0	N
Neg. Controls	(+)	(-)	(-)	(-)	0	N

Positive control, SCG #1, was toxic at a dilution of 1:16 at 24 hours.

Conclusion: Nontoxic

Date Prepared: 2-22-94 Date Terminated: 2-26-94

CL Completed 2-28-94 Tech. PRP/CP/VS/LV Approved For: Laiani D. Venegas, B.S.

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ID NO. AP #03-522

HEMOLYSIS TEST *IN VITRO*

Test Article: Peek 381 G

Procedure: Direct Contact Method: The test article was cut into small chips or lengths and 0.5 gram(s) placed in individual extracting tubes containing 10 ml of 0.9% sodium chloride solution.

To duplicate tubes containing the prepared test article and to a similarly treated set of positive and negative control tubes was added 0.2 ml of rabbit blood previously collected in a vacuum tube containing E.D.T.A. The tubes were inverted gently to mix the contents, then placed in a constant temperature water bath at 37°C for 1 hour. The blood-saline mixture, positive and negative controls were then centrifuged for 10 minutes at a speed of not less than 1000Xg.

The absorbance of each test article solution was determined spectrophotometrically at 545 nm. Similarly, absorbances were recorded for the positive control (10 ml water and 0.2 ml blood) and the negative control (10 ml 0.9% sodium chloride solution and 0.2 ml blood).

Results: Test #1 = 0.3% hemolysis
Test #2 = 0.2% hemolysis

Mean Hemolysis = 0%

Under the conditions of this test, the test article would be considered nonhemolytic.

Date Prepared: 2-24-94 Date Completed: 2-24-94

EPD Completed 2-25-94 Tech. PRP/MC/LV Approved For: Laiani D. Venegas, B.S.

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